VZCZCXRO3889
PP RUEHDA
DE RUEHAK #5335/01 2580453
ZNR UUUUU ZZH
P 150453Z SEP 06
FM AMEMBASSY ANKARA
TO RUEHC/SECSTATE WASHDC PRIORITY 8672
INFO RUCPDOC/USDOC WASHDC PRIORITY
RUEHIT/AMCONSUL ISTANBUL 1267
RUEHDA/AMCONSUL ADANA 1097
RUEHBS/USEU BRUSSELS

UNCLAS SECTION 01 OF 02 ANKARA 005335

SIPDIS

DEPT PLEASE PASS USTR FOR LERRION/BPECK
DEPT PLEASE PASS USPTO FOR JO ELLEN URBAN
USDOC FOR ITA/MAC/CRUSNAK
USEU FOR CHRIS WILSON

SENSITIVE
SIPDIS

E.O. 12958: N/A
TAGS: ETRD KIPR USTR EUN TU
SUBJECT: TURKEY: PHRMA INDUSTRY DATA EXCLUSIVITY UPDATE

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Ref: (A) Ankara 1898 and previous

¶1. (SBU) Summary: According to PhRMA company representatives in Turkey, an August 3 Turkish MOH letter to the EU has specifically acknowledged data protection for 22 of the 67 molecules for which data exclusivity (DE) had been ambiguous under Turkey's new DE regulations (ref A). The remaining 45, however, are not covered by DE for various reasons. State Minister for Foreign Trade Kursad Tuzmen will meet with PhRMA in D.C. on September 15 to discuss this issue. Pharmaceutical companies are urging the EU to delay opening of accession negotiations on the "Free Movement of Goods" and "Intellectual Property Rights" chapters of the acquis communitaire until Turkey has met its IPR obligations. End summary.

THE GOOD NEWS

¶2. (SBU) According to representatives of research-based pharmaceutical companies in Turkey, Turkey's MOH provided confirmation to the EU in an August 3 letter that the confidential test data for 22 of the 67 molecules for which data exclusivity (DE) had not been assured by the GOT (now increased from the previous 45 to a total of 67) would be protected. This correspondence resulted from a special June 30 EU meeting with Turkey's health officials in Brussels that followed GOT approval of a generic copy of one of Danish firm Lundbeck's products (ref A) that the companies believed should have benefited from DE. EU officials in Brussels reportedly referred to this approval as a "clear violation" of Turkey's Customs' Union obligations. This information represents the first written communication from the MOH specifically addressing DE since research-based pharmaceutical companies submitted their list of molecules whose status was not clear under the new regulations in ¶2005.

THE BAD NEWS

¶3. (SBU) Also in this MOH letter was a list of the 45 remaining molecules that would not receive data exclusivity and the reasons why the MOH was not granting this protection:

-- 22 because generic applications were filed before the January 1, 2005 start of Turkey's stronger data protection legislation;

-- 6 because the original innovative product has not yet been approved in Turkey;

-- 7 (which had previously been granted DE) because the original innovative product has not yet been registered in Turkey;

-- 1 because it was a vaccine;

-- 3 because it was a "combination product";

-- 1 because a generic was already on the market in Turkey;

-- 5 because they either were not eligible for DE in the EU or because they were licensed in the EU prior to 2001 (in which case the six years DE will expire at the latest by the end of this year).

¶4. (SBU) PhRMA company officials in Turkey plan to meet with MOH officials for clarification on this decision. For those molecules that were denied DE because the original product has not yet been approved in Turkey, it appears that this violates current Turkish domestic legislation because DE protection was linked to the original product's approval in any EU country.

NEXT STEPS

¶5. (SBU) PhRMA companies in Turkey learned about the August 3 letter in early September, only a few days after they submitted a letter to USTR in support of the retention of Turkey's GSP benefits. While company officials tell us that they still support this position, they are concerned that it could send the wrong message to the GOT. State Minister for Foreign Trade Kursad Tuzmen, who is conducting a trade mission to the U.S. during the week of September 11 to promote his "Year of America" strategy, will meet with PhRMA in D.C. on the morning of September 15.

¶6. (SBU) EU representatives in Ankara told PhRMA officials that the

EU plans to send another "strongly worded" response to the GOT in light of this new information. Included in this letter will be a call for a moratorium on the approval of generic applications for the molecules still in question. This information will also be included in the EU's November progress report on Turkey's accession process. Finally, pharmaceutical company representatives and interest groups are urging the EU to delay the beginning of accession talks regarding the "Free Movement of Goods" and "Intellectual Property Rights" chapters until the GOT meets its IPR obligations.

COMMENT: MOH STILL THE PROBLEM

¶7. (SBU) Foreign Ministry and Foreign Trade officials understand Turkey's IPR obligations and appear committed to working to fix the problem. As with many trade issues in Turkey, however, the ministries who hold responsibility for complying with international agreements have limited ability to effect a change in domestic policy. It is clear that domestic generics manufacturers are continuing to exert political pressure on the government. In our recent meetings with MOH officials, they have not communicated either an understanding of the need for greater data protection than what is currently allowed or the will to fix the problem. In addition to continued engagement with FTU, MFA and MOH officials, we have suggested that company representatives consider discussing the issue with Turkey's EU Secretariat office (which coordinates EU accession negotiations) and with the PM's advisors. We will continue to raise this issue at all levels. End comment.

WILSON